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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,727

07/03/2007

Henrik Stender

119880-00402

6468

86738

7590

11/08/2011

MCCARTER & ENGLISH, LLP BOSTON

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

11/08/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,727	Applicant(s) STENDER ET AL.	
	Examiner Patricia A. Duffy	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11-29-2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 4-13, 25, 26, 51-60 and 63-65 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 25, 26, 51, 64 and 65 is/are allowed.
- 7) ☒ Claim(s) 4-13, 52-60 and 63 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2010; 2011</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11-29-2010 has been entered.

Any objections/rejections not reiterated herein are withdrawn based on Applicants amendments to the claims.

Information Disclosure Statement

The information disclosure statements filed 8-2011 and 10-21-2011 have been considered. Initialed copies are enclosed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

A claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claim 4-13, 52-60, 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim language of claim 25 and 51 is closed. The claim language of claims 4-13 as dependent thereon recite comprising so the metes and bounds of the claim cannot be ascertained. A claim which depends from a claim which "consists of" the recited elements or steps cannot add an element or step. MPEP 2111.03 Similarly, claim 60 recites an additional probe to the probe set of the claims. As such, this limitation does not further limit the claims. Additionally, claim 60 is confusing since the preamble of claim 51 recites "suitable for performing an assay for analysis of one or more *Staphylococcal* species other than *S. aureus* in a sample". What is a probe for *S. aureus* in the probe set/kit when the kit appears to excludes such.

As to claim 52-59, the claims recite method steps or use a single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. *IPXL Holdings v. Amazon.com, Inc.*, 430 F.2d 1377, 1384, 77 USPQ2d 1140, 1145 (Fed. Cir. 2005); *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990) where the claims were directed to an automatic transmission workstand and the method of using it held ambiguous and properly rejected under 35 U.S.C. 112, second paragraph.

As to claim 63, the claim references a PNA probe that is 15 or 16 nucleotides in length. Do applicants intend to mean nucleobases? PNA probes do not have the phosphodiester/sugar backbone of a nucleotide (see Ray et al *The FASEB Journal*, 14:1041-1060, June 2000; of record). As such, the reference to nucleotides in a PNA probe is confusing and internally inconsistent with the routine use of the term in the specification and the art.

Claims 4-13 and 52-56 are rejected under 35 U.S.C. 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of the a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

As to claim 4-13, the claims fail to further limit the structure of the probe set of claim 25.

As to claims 52-56 as depending from claim 51 recite method steps or goals. These method steps/goals do not further limit the structure of the kit. As such, these claims are not further limiting.

See the "Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications" (Federal Register, Vol. 76, No. 27, Wednesday, February 9, 2011), pg 7166, section "5. Dependent Claims", which states that "If the dependent claim does not comply the with the requirements of § 112, ¶4, the examiner should reject the dependent claim under § 112, ¶4 as unpatentable rather than objecting to the claim" and "a dependent claim must be rejected under § 112, ¶4 if it omits an element from the claim upon which it depends or it fails to add a limitation to the claim upon which it depends".

Status of the Claims

Claims 4-13, 52-60 and 63 stand rejected. Claims 25, 26, 51, 64 and 65 are allowed.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor Gary Nickol can be reached at 571-272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Primary Examiner